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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/709,170 | 11/10/2000 | Raymond P. Warrell | 10412-025 | 4982 |

7590 03/26/2004
Patrick J. Birde, Esq.
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EXAMINER

GIBBS, TERRA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1635

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/709,170

Applicant(s)

WARRELL ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.


Claim(s) rejected: 1-23 and 29-33.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 5. does NOT place the application in condition for allowance because: The 35 U.S.C. 102(b) rejection of record against claims 1-5 and 13-18 as being anticipated by Webb et al. would be maintained for the reasons of record set forth in the previous Office Action filed December 15, 2003. In response to the 35 U.S.C. 102(b) rejection, Applicants argue that Webb et al. teach a one two-week course of treatment. Applicants contend that the Examiner's interpretation of a cycle of therapy is contrary to the meaning of a cycle of therapy as known and used by one skilled in the art. Applicants rely on a page from the American Cancer Society web site that describes a cycle of therapy as "A cycle may involve one dose followed by several days or weeks without treatment". Applicants arguments have been considered, but are not found persuasive. The issue at hand is the interpretation of a cycle of therapy. The Examiner has defined "cycle" according to Applicant's Specification at page 7, lines 28-35 where it recites, "cycle" refers to a period during which a single therapeutic or sequence of therapeutics is administered. Applicant is relying on a page from the American Cancer Society web site to describe a cycle of therapy as "a cycle may involve one dose followed by several days or weeks without treatment". This definition is selective and contrary to Applicants defined term in the instant specification. Therefore, "cycle" as recited by Applicant's specification, is broadly defined to encompass the cycle(s) of therapy taught by Webb et al. It is noted that using the defined meaning of the term "cycle" as recited in the instant specification at page 7, lines 28-35, the cycle(s) of therapy taught by Webb et al. are not excluded from the cycle(s) of therapy recited in the instant claims. Similarly, all of the claim rejections under 35 U.S.C. 103 relying on a combination of Webb et al. and other references, would be maintained for the reasons of record set forth in the previous Office Action filed December 15, 2003. In response to the 35 U.S.C. 103 rejection, Applicants argue that Webb et al. do not teach one or more cycles of therapy consisting of 2 to 13 days. This is not found persuasive because using the defined meaning of the term "cycle" as recited in the instant specification at page 7, lines 28-35, the cycle(s) of therapy taught by Webb et al. are not excluded from the cycle(s) of therapy recited in the instant claims, as argued above. KAL
01-24-04

Continuation of 10. Other: The 35 U.S.C. 102(b) rejection against claims 1-5 and 13-18 as being anticipated by Webb et al. would be maintained for the reasons of record set forth in the previous Office Action filed December 15, 2003. Similarly, all of the claim rejections under 35 U.S.C. 103 relying on a combination of Webb et al. and other references, would be maintained for the reasons of record set forth in the previous Office Action filed December 15, 2003. KAL
01-24-04


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER